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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FISH & RICHARDSON P.C.
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
07/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/063,159	AKERLUND ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-13,15,17-21,23-26 and 28-49* is/are pending in the application.

4a) Of the above claim(s) *2,4-7,11,18,23-25,29,34-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,8,10,12,13,15,17,19-21,26,28 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 May 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 12 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Quick et al. (US Patent No. 3,976,073). Quick discloses a fluid transfer assembly for use in an infusion system (Figs. 1-4), said assembly comprising: a fluid container (40) having an infusion fluid, a drug container (12) having a medical substance, at least one fluid barrier controlling fluid passage between said drug container and said fluid container (barrier 39 in Fig. 2 does not allow fluid flow between the two until 38 is ruptured), said fluid container further comprising at least one inlet port for receiving said medical substance from said drug container, wherein said at least one inlet port comprises a protruding resilient tube (Fig. 4, the resilient tube/inlet port is tube 22 which extends from 40), a hollow spike member arranged to be retained inside said protruding resilient tube of said inlet port and provided with a first luer-lock connector (Figs. 1-4, the examiner is interpreting the spike member to be 20 as it is structurally equivalent to Applicant's hollow spike member. 20 is arranged to be retained inside the resilient tube 22 when the assembly of Fig. 1 is attached/pushed onto the resilient protruding tube 22 in Fig. 4. Spike 20 has an attached luer lock connector (portion 44 in Figs. 2 and 3)), said drug container further comprising a cap for sealing said drug container (Figs. 2 and

3, element 37 can be interpreted as the cap as this is what covers the end of the container and seals the container with the medication), said cap further comprising a second luer lock connector for attachment to said first luer lock connector (cap portion has luer lock portion 42 which mates with the luer lock connector that is attached to the spike), and wherein said at least one fluid barrier is designed and arranged to be ruptured by an external force to allow said fluid passage (the act of end portion 24 rupturing fluid barrier 38 is performed externally relative to the fluid container. Please note that Applicant has not claimed what the force must be external relative to. Also, col. 2, lines 15-17 disclose that portion 24 ruptures 38).

In reference to claim 3, Quick discloses that the cap further comprises a protruding member forming a second fluid duct between said drug container and said second luer lock connector wherein a fluid barrier is provided inside said second fluid duct (the fluid duct extending between the bottom portion of 37 and the top portion of 37 can be interpreted as the second fluid duct as it contains the fluid barrier 38).

In reference to claim 12, Quick discloses that the drug container further comprises a neck, said cap further comprising a protruding member forming a second fluid duct between said drug container and said second luer-lock connector, said cap further comprising locking members for grasping said neck (Figs. 2 and 3).

In reference to claim 19, Quick discloses that the cap further comprises a protruding member forming a second fluid duct between the drug container and said second luer lock connector (Figs. 2 and 3 disclose that the extending portion between the bottom and top portions of 37 can be interpreted as the second fluid duct), said fluid

barrier being provided inside said second fluid duct (38), said drug container comprising a rigid material (12), said protruding member comprising a more flexible material than said second luer-connector and said drug container (col. 3, line 12 discloses that 14 is elastomeric), and said fluid barrier comprising a more brittle material than said drug container, said protruding portion, and said second luer lock connector (38 is rupturable and is therefore made of a more brittle material).

Claims 21, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Quick et al. (US Patent No. 3,976,073). Quick discloses a drug container for use in an infusion system (Figs. 1-4, 12), said drug container comprising: a fixed dose of a medical substance (Figs. 1-4), and a cap for sealing said drug container (37 can be interpreted as the cap as this is what seals the medication within container 12), said cap further comprising a luer lock connector (portion 42) for attachment to a corresponding connector provided on a hollow spike that is arranged to be retained inside a protruding resilient tube (42 connects with luer lock 44 which is attached to spike 20 which is held within resilient tube 22 in Fig. 4 when the spike assembly is attached to the resilient protruding tube 22) of an inlet port of a container for infusion fluid (Fig. 4, container 40), thereby creating a luer lock coupling (Figs. 2 and 3 disclose the luer lock coupling between the luer lock connectors), said cap further comprising a protruding member forming a fluid duct between said drug container and said second luer connector (cap portion has a protruding portion which extends up from 37 which forms a fluid duct when

connected to the other luer lock), wherein a fluid barrier is able to be ruptured by an external force is provided inside a second fluid duct (the second fluid duct could be interpreted as the duct portion within 37 and this portion at least partially contains rupturable barrier 38 in which the act of end portion 24 rupturing fluid barrier 38 is performed externally relative to the fluid container. Please note that Applicant has not claimed what the force must be external relative to. Also, col. 2, lines 15-17 disclose that portion 24 ruptures 38).

In reference to claim 30, Quick discloses that the drug container further comprises a neck, said cap further comprising a protruding member forming a second fluid duct between said drug container and said second luer-lock connector, said cap further comprising locking members for grasping said neck (Figs. 2 and 3).

In reference to claim 32, Quick discloses that the cap further comprises a protruding member forming a second fluid duct between the drug container and said second luer lock connector (Figs. 2 and 3 disclose that the extending portion between the bottom and top portions of 37 can be interpreted as the second fluid duct), said fluid barrier being provided inside said second fluid duct (38), said drug container comprising a rigid material (12), said protruding member comprising a more flexible material than said second luer-connector and said drug container (col. 3, line 12 discloses that 14 is elastomeric), and said fluid barrier comprising a more brittle material than said drug container, said protruding portion, and said second luer lock connector (38 is rupturable and is therefore made of a more brittle material).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8, 10, 20, 26, 28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quick et al. (US Patent No. 3,976,073) in view of Scarrow (US Patent No. 5,061,264). Quick discloses the device substantially as claimed except for the second luer lock connector having a pierceable closure for protection before use, the cap having a hollow needle for penetrating the cap's closure, the drug container being made of glass or a rigid polymer material. Scarrow, however, discloses a similar fluid transfer assembly (Fig. 1) in which the drug container is made from glass (col. 3, line 65 discloses the drug container is glass), the second luer lock connector has a pierceable closure to protect it before use (72) and the drug container cap has a hollow needle for penetrating the closure (70). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Quick's device with a

pierceable closure and needle so that the drug container and the second luer lock remain sterile before use to protect the patient's health, and to make the drug container from glass as it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Claims 13 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quick et al. (US Patent No. 3,976,073) in view of Haber et al. (US Patent No. 5,593,028). Quick discloses the device substantially as claimed including a rupturable fluid barrier (38), however, Quick does not disclose that the barrier is a brittle polymer. Haber, however, discloses a rupturable barrier comprises of a brittle polymer dividable along a weakening line by said external force (col. 7, lines 5-16). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Quick with the brittle barrier, as taught by Haber, in order to provide a barrier that is assured to break upon the external force applied, in order to assure that the flow between containers takes place during a critical medical infusion to a patient.

Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quick et al. (US Patent No. 3,976,073 in view of Vaillancourt (US Patent No. 5,897,526). Quick discloses the device substantially as claimed including a protruding member forming a second fluid duct between said drug container and said second luer

lock connector (protruding portion extends upwards from 37), however, Quick does not disclose a clamping members or an infusion line. Vaillancourt, however, discloses a clamping members (Fig. 14, 22' and 55) as well as an infusion line (12) attached to the inlet port. The clamping members could be used on the neck portion of (28) to compress the protruding member, thereby closing said second fluid duct and preventing undesirable fluid passage between said second luer lock connector and said drug container, and the infusion line could be used at the inlet port to allow the medication/fluid to be infused into the patient. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Quick with the clamping member and infusion line, as taught by Vaillancourt, in order to provide a means for delivering the medication as well as to provide a means for stopping flow in the even that flow between the drug container and the fluid container needs to be suddenly stopped.

Response to Arguments

Applicant's arguments with respect to claims 1, 3, 8, 10, 12, 13, 15, 17, 19-21, 26, 28, 30-33 have been considered but are moot in view of the new ground(s) of rejection. The amendments made to the independent claims have overcome Scarrow as a primary reference and therefore a new primary reference (Quick) is being used. However, as described in the rejections above, it is still the examiner's position that the following references can be used as secondary references (Vaillancourt, Haber and Scarrow).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767